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Dr. Ruth Solomon
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Dear Dr. Solomon,

I want to comment on the draft document regarding use of Genetic Systems FDA approved kits for screening cadaveric blood samples for HIV I/II and Hepatitis B Surface Antigen. Several points should be considered.

The Center for Organ Recovery & Education (CORE) is a full-service organ procurement organization that coordinates the recovery of organs, tissue and eyes/corneas for transplantation and/or research. CORE has its own in-house CLIA-accredited laboratory that has been in operation since 1997.

CORE laboratory currently uses the Abbott Quantum system for screening cadaveric samples from a percentage of our tissue and eye donors. A percentage of these donors are obtained prior to pronouncement of death and are not considered cadaveric by the FDA definition. In some cases, our laboratory is fortunate enough to receive a recently collected pre-transfusion/pre-infusion sample from the hospital laboratory where the individual received emergency treatment or the sample was collected at the time of brain death determination when the individual was being evaluated for organ, tissue and eye donation.

Abbott has been a leader in Hepatitis and HIV EIA screening for quite some time and physicians, laboratory users and managers all over the country trust the results.
I carefully reviewed the package inserts from both Genetic Systems HIV I/II and Hepatitis B Surface Antigen kits for the purpose of complying with the FDA January 31, 2001, implementation guideline. It troubles me that in the literature Genetic Systems qualified only 66 cadaveric samples in order to reach a conclusion that their kits perform with accuracy using these type samples. Would you not agree that if our organization

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alone analyzed more than 2,000 samples over the past three years (utilizing the Abbott Quantum EIA test kits) and have not had one reported recipient adverse reaction that should be a consideration on reliability of the assay regardless of the vendor? Isn't a positive recipient outcome why we are all concerned with the field of transplantation and donor screening? I am not disputing the accuracy of the data, however, I do question the conclusion that Genetic Systems is the only company that can give reliable test data from cadaveric samples. If another company's test kits (prior to gaining FDA cadaveric sample approval) can be compared to what is now deemed the standard (Genetic Systems) and that data correlates, then why not permit the laboratory to use those kits for screening purposes at least until the market opens up. Would the FDA propose that just because a sample is hemolyzed or demonstrates a degree of lipemia, as is the claim with cadaveric samples, that regardless of the source of the specimen (cadaveric or non-cadaveric) that an FDA kit approved for hemolysis or lipemia be utilized? Most companies have fairly extensive data and make package insert claims on sensitivity and specificity with hemolyzed, icteric and lipemic samples.

I proceeded with my evaluation and invited Genetic Systems into my laboratory to perform a comparison study on its HIV I/II and Hepatitis B Surface Antigen kits against the Abbott Quantum kits. Fifty cadaveric samples were tested in our recent comparison study. Upon review of the data, all 50 results were in agreement utilizing both company's kits. I then question: Why is it not acceptable for us to document that the Abbott Quantum test kits performed as expected and continue to use Abbott for our donor screening?

Further, from a technical standpoint Abbott assays are much easier to perform than the Genetic System assays. Many experienced EIA users prefer the Abbott HIV I/II and Hepatitis B Surface Antigen bead technology to the more troublesome micro titer plate assays. Abbott Quantum technology consists of adding serum or plasma to a test well; dropping a test bead; adding a cover; followed by a series of wash/substrate additions and incubation steps. In addition, the Abbott Quantum HIV I-II and Hepatitis B Surface Antigen assays do not require a serum/plasma dilution, as does Genetic Systems with its pre-dilution step leaving more room for technical error.

From a financial standpoint, Genetic Systems is the only company that has gained FDA approval for the HIV I-II and Hepatitis B Surface Antigen currently making it a monopoly on pricing. Genetic Systems is not able to market these assays at a cost comparable to the Abbott Quantum kits. If I purchase HIV I-II and Hepatitis B Surface Antigen kits from Genetic Systems my organization would realize a 44% increase in kit cost. That increase is because the micro titer plates provided by Genetic Systems consist of ten strips with eight test wells per strip. The test strips do not have individual breakaway wells. Consequently, each strip incompletely utilized will result in lost revenue and/or additional direct cost. Also, Genetic System's smallest test kit available is 480 tests/kit versus Abbott's 100 test/kit. Genetic Systems does not market to small volume laboratories. Small volume laboratories are a very important aspect in the corneal transplant field because of placement concerns and emergency cases. The larger reference laboratories cannot and will not provide the type of stat service organizations like CORE

require to meet surgical needs and reduce corneal shelf life. In our experience, it is very uncommon to place a cornea with a surgeon that has a shelf life much over three days.

For my laboratory to remain cost effective and provide stat testing, Genetic Systems would have to provide me with one free test kit for every two kits that I purchase, which is not feasible. Genetic Systems would additionally charge me for equipment rental. For my laboratory to switch to the two approved Genetic Systems assays, I would have to acquire an incubator, two plate washers, two printers and two ELISA plate readers. The washers, printers and readers are available for an additional reagent rental fee further increasing my direct costs. I would have to continue to use Abbott test kits for those tests not available from Genetic Systems.

In conclusion, if my 50 sample parallel studies were not in 100% agreement between Abbott and Genetic Systems, I could justify immediately converting; however, I am extremely troubled that Genetic Systems based its entire cadaveric study for FDA approval on the previously mentioned 66 cadaveric samples (only 16 more samples than I recently compared) and saw no difference in results.

I suggest that if a laboratory can prove through extensive parallel studies that the system it has in place performs as well or better than one that has gained FDA approval, then that laboratory should be able to continue to use its current test system at least until several other vendors obtain FDA approval and a broader menu of tests. The cost per kit would then drop once the consumers had a choice of vendors. Many of the tests performed by our laboratory are not available from Genetic Systems such as HTLV I-II, Hepatitis B Core Total, and HIV-Ag. As a result I would have to maintain equipment and kits from several vendors in order to perform our standard serology panel resulting in a financial burden as well as a technical burden.

Thank you for allowing me to state my questions and concerns. I look forward to hearing from you.

Respectfully yours,

Karen A Brown

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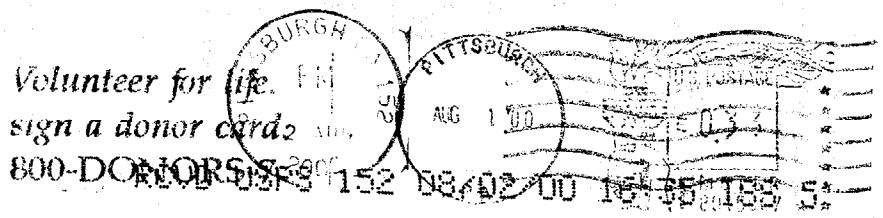

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